

PATENT
10/023,969
Docket 084/002

REMARKS

This paper is responsive to the Office Action dated April 21, 2003 (Paper No. 7), which is the first action on the merits of the application.

Claims 1-15 were previously pending in the application; claims 1-4, 7, and 9-11 were under examination. The other claims are subject to a request for rejoinder. Upon entry of this Amendment, claims 16-25 are added. New claims 16, 17, 20, 22, and 23 fall within the group under examination, and the other new claims fall within the same groups as some of the withdrawn claims. Accordingly, claims 1-4, 7, 9-11, 16-17, 20, and 22-23 are now under examination.

Applicant gratefully acknowledges consideration of the Information Disclosure Statements (Papers 3 and 4). Applicant also gratefully acknowledges approval of the drawings and sequence listing.

Reconsideration and allowance of the application is respectfully requested.

Amendments:

A limitation previously appearing in claim 7 has now voluntarily been incorporated into claim 1, as relating to embodiments of the invention of particular current commercial interest.

Claims 16 and 17 are supported by claims 3 and 4 as originally filed, now presented in independent form. Claims 18-25 mirror claims 5-9 and 13-14. Accordingly, no new matter is introduced into the application as a result of entering these amendments.

The website referred to on page 13, line 17 was not intended as a hyperlink. Nevertheless, the reference to the GenBank website has now been amended. Should the skilled reader wish to find their way to the GenBank website to obtain the sequence referred to, they may readily find it using a suitable search engine or published internet directory.

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Rejection under 35 USC § 112 ¶ 2

Claim 7 stands rejected for the use of parenthesis.

Applicant respectfully maintains that the format previously presented was an acceptable format.

However, claim 7 has now been amended, since features of claim 7 as originally presented have now been incorporated into claim 1. Claim 7 now requires that the heterologous gene be under control of the tissue or tumor specific transcriptional control element. Claim 1 indicates only that the heterologous gene and tissue or tumor specific transcriptional control element are both present in the virus.

Rejections under 35 USC § 102, and Double Patenting

Claims 1-2, 7, and 9-11 stand rejected under 35 USC § 102(e) as being anticipated by a patent application by Schiff (US 2002/0128221 A1). Claims 1-2, 7, and 9-11 stand rejected under 35 USC § 102(a) as being anticipated by Morin et al. (WO 00/46355). Claims 1-2, 7, and 9-11 stand rejected under 35 USC § 102(B) as being anticipated by Henderson et al. (U.S. Patent 5,871, 726). Claims 1-2, 7, and 9-11 also stand provisionally rejected under the judicially created doctrine of double patenting as unpatentable over particular claims of copending USSN 09/994,427 (Schiff).

All of these rejections are made on the supposition that replacing the [endogenous E1a] promoter with another promoter (such as the hTERT promoter described in Schiff or Morin et al.; or the prostate-specific response element of Henderson et al.) would fall within what was meant by replacing the function of the adenovirus E1a gene with a heterologous gene.

Applicant respectfully disagrees. A promoter may be referred to as a "gene sequence" or a "gene element". However, a promoter by itself does not meet the usual meaning of what is meant by a "gene". Accordingly, replacing the E1a promoter with an hTERT or prostate-specific promoter would not constitute replacing a function of the adenovirus E1a gene with a heterologous gene. As described throughout the application, the invention claimed in this application involves incorporating a heterologous gene producing a heterologous gene product that replaces a function of the E1a gene.

Nevertheless, to facilitate prosecution of the application, the claims have now been amended to render the meaning of the claim more explicit. Specifically, claim 1 now indicates that a function of the adenovirus E1a gene is replaced by an encoding region from at least one heterologous gene. This is supported throughout the specification as originally filed (such as Example 4, page 17 ff.).

Withdrawal of these rejections is respectfully requested.

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Claim Objections:

Claims 3 and 4 stand objected to as depending from a rejected claim. Otherwise, these claims are indicated as being in condition for allowance, for which applicant is grateful.

Claims 3 and 4 as originally filed are now presented in independent form as claims 16 and 17, incorporating the limitations originally presented in claim 7. Furthermore, for reasons indicated earlier, applicant maintains that claim 1 is allowable. Accordingly, claims 3, 4, 16, and 17, are also believed to be in condition for allowance.

Request for Rejoinder:

Applicant acknowledges with gratitude reconsideration of the restriction requirement, with the determination that claim 13 links groups III-VIII.

Species A-E and F-R are linked by way of claim 1. Applicant hereby requests that claims respecting the non-elected species be rejoined into the group under examination upon determination that claim 1 is patentable.

Claims 12-15 are method claims that depend from and incorporate the limitations of product claims 1-11. Applicant hereby renews the request that these claims (and all other method claims depending from product claims in the elected group) be rejoined, upon determination that the product claims are patentable, in accordance with MPEP § 821.04.

Conclusion


Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

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Should the Patent Office determine that an extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Assistant Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,



J. Michael Schiff
Registration No. 40,253

GERON CORPORATION
230 Constitution Drive
Menlo Park, CA 94025
Telephone: (650) 473-7715
Fax: (650) 473-8654

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